UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,532	10/23/2003	Michel Therin	114139	9106

25944 7590 02/01/2007

OLIFF & BERRIDGE, PLC
P.O. BOX 19928
ALEXANDRIA, VA 22320

EXAMINER	
TYSON, MELANIE RUANO	
ART UNIT	**PAPER NUMBER**
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,532	THERIN ET AL.	
	Examiner	Art Unit	
	Melanie Tyson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on 11 December 2006.

Corrections made to the specification and claims are accepted.

Response to Arguments

1. Applicant's arguments with respect to claims 1-4 and 6-17 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-8, 11, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (Publication No. 2003/0023316) in view of Carr et al. (2002/0095218 A1). Brown et al. disclose a rectangular porous textile support (Figure 1, paragraph 19) comprising a two-dimensional structure (two-dimensional fibrous matrix construct; paragraph 60), an arrangement of threads (Figure 1, element 28) constituting

a knitted structure (paragraph 19) each composed of at least one filament of nonabsorbable material (polyethylene; paragraph 50), where the support defines the free edges of the part (end portions 30), and a hydrophilic absorbable material (small intestine submucosa 12; paragraph 6) covering the textile support (coupled to or "bonded"; paragraph 20) on both of its sides (top 16 and bottom 18) extending across the surface (from a first end 20, including sides 24, through a second end 22) and creating on each side two unprotected zones (end portion 30 adjacent the first end of the protected zone 20 and end portion 30 adjacent the second end of the protected zone 22) that are limited by the free edges (end portions 30) and are free of any absorbable material (12) and a protected zone (from the first end 20, including sides 24, through the second end 22) that represents a central band of the part, since it is a strip through the center of the part. Furthermore, the textile support defines a "microporosity" since it is inherent that there are holes between the overlapping fibers and/or holes between filaments within the same thread, and defines a "macroporosity", since Figure 13 clearly shows holes between non-contacting threads.

Although Brown et al. disclose the absorbable material *comprises* collagen, Brown et al. do not disclose it is selected from the group *consisting* of modified collagens, polysaccharides, and their mixtures. Carr et al. disclose a tissue prosthesis comprising a hydrophilic absorbable material (paragraphs 2 and 17). Carr et al. teach that the absorbable material *consists* of modified collagen: intestinal collagen layer from a mammalian source is mechanically cleaned to remove muscular layers (paragraph 27), chemically cleaned to *remove debris and other substances other than collagen*

(paragraph 28), decontaminated and disinfected (paragraph 29), and then finally modifying the collagen through cross-linking (paragraph 32). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize modified collagens in the support of Brown et al. as taught by Carr et al. in order to provide a prosthesis that is biocompatible with the host's cells (paragraphs 16), and a prosthesis that is strong and durable, thus improving the handling of the prosthesis (paragraph 32).

Brown et al. in view of Carr et al. disclose the composite part described above may be used for soft tissue reinforcement (paragraph 10). Brown et al. in view of Carr et al. further disclose the composite part may be cut, trimmed, and shaped to accommodate a particular application (end of paragraph 76). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to cut the composite part of Brown et al. in view of Carr et al. along a line (defining a strip with parallel edges, since Figure 1 shows a part with straight parallel edges) from a first free edge (end portion 30), through the first (20) and second (22) ends of the protected zone, and out through a second free edge (end portion 30) in order to obtain a composite reinforcement prosthesis of the appropriate size and shape for the intended application.

Furthermore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide a strip with parallel edges curved in an arch. Applicant has not disclosed that a strip with edges curved in an arch provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary

skill in the art, furthermore, would have expected applicant's invention to perform equally well with straight edges because the function of the strip is to act as a reinforcement prosthesis, and this function is not affected by its shape. Therefore, it would have been obvious to modify the shape of the strip of Brown et al. to obtain the invention as specified in claim 16.

5. Claims 9, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. in view of Carr et al. as applied to the claims above, and further in view of Browning (Publication No. WO 02/078568 A1).

Brown et al. in view of Carr et al. disclose a part as described above, however, do not disclose the absorbable material covers the textile support by means of a coating. Browning discloses a textile support (Figure 8b, element 20). Browning discloses the absorbable material covers the textile support by means of a coating (page 37, line 31, and page 38, lines 1- 2), where the strands (22) of the support (20) may be entirely embedded in the absorbable coating (32) such that the outer surface of the mesh is covered entirely by the absorbable coating (page 38, lines 8-11). Therefore, it is obvious that the absorbable coating (32) occludes the microporosity of the textile support (the holes between the overlapping fibers and/or the holes between filaments within the same thread). Browning further discloses that the absorbable coating may be applied to both sides of the support (top and bottom) so that the support is encased and has no holes or gaps on either side (page 38, lines 13-17). Therefore, it is obvious the coating occludes the macroporosity (holes between non-contacting threads) of the support (20).

Covering the support with an absorbable material by means of a coating as taught by Browning reduces the likelihood of bacteria becoming lodged on the strands of the support before implantation of the support (page 8, lines 17-20). Furthermore, coating the support makes it more substantial and less flexible such that it is easier to handle (page 38, lines 20-22). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to cover the support with an absorbable material by means of a coating as taught by Browning in order to make the part less susceptible to bacteria and easier to handle during implantation.

Figure 1 of Brown et al. shows the part is rectangular, wherein the protected zone (from the first end 20, including sides 24, through the second end 22) represents a central band of the part, since it is a strip through the center of the part. It is obvious that when the absorbable material covers the support by means of a coating (as taught by Browning), the protected zone becomes occluded (for the same reasons described above), thus producing an occluded zone (vice a protected zone) that represents the central band of the support.

6. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. in view of Carr et al. as applied to the claims above, and further in view of Landgrebe et al. (EP 0774240 A1).

Brown et al. in view of Carr et al. disclose a part as described above, however, do not disclose a strip with nonparallel edges. Landgrebe et al. disclose a strip (Figure 1, not labeled) having nonparallel edges (top edge 2 and bottom edge not labeled). Figure 1 shows the device is bulged in the central region (1) and narrower at the ends

(5, 6, 7, and 8). This configuration allows the device to support a wide surface area of an organ (bladder; column 1, lines 45-47), thus contributing to a reliable treatment of incontinence in cases of extreme weakness of the pelvic floor with prolapsing anatomical displacement of the organs of the lesser pelvis (column 1, lines 33-39). Therefore, to construct the strip of Brown et al. in view of Carr et al. having nonparallel edges and a bulge as taught by Landgrebe et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to support prolapsed structures on a large surface area.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 6, 8-14, and

16-18 of copending Application No. 10/690625. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are merely more specific than the instant application claims, and they substantially claim the same invention. The structural limitations set forth in claims 1-17 of the instant application are also claimed in the copending application, e.g., a porous textile support, an arrangement of threads, at least one filament composed of nonabsorbable polymer material, a hydrophilic absorbable material covering the textile support.

In claims 14-17, the application requires the composite part to be cut along a cutting line to produce composite parts of alternate shapes. The copending application includes the alternate shapes, but fails to specifically state that the composite part is cut along a cutting line. It is considered obvious to cut, trim, and shape a composite part, as this is simply a way to accommodate a composite part for the intended application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Friday 9:00 a.m. - 5:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson MT
January 27, 2007

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
1/31/07